

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

GILEAD SCIENCES, INC. and  
EMORY UNIVERSITY,

Plaintiffs,  
v.

MYLAN INC. and MYLAN  
PHARMACEUTICALS INC.,

Defendants.

Civil Action No. 1:14-cv-99 (IMK)

**GILEAD'S MOTION TO DEFER CONSIDERATION OF MYLAN'S  
INDEFINITENESS ARGUMENT OR, ALTERNATIVELY, FOR  
LEAVE TO FILE A REPLY**

## I. INTRODUCTION

Plaintiff Gilead Sciences, Inc. (“Gilead”) respectfully moves to defer consideration of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.’s (collectively, “Mylan”) indefiniteness argument—*raised for the first time* in Mylan’s Answering Claim Construction Brief—until after the conclusion of fact and expert discovery. In the alternative, if the Court is inclined to consider Mylan’s indefiniteness argument during claim construction, then Gilead requests leave to file a reply brief and supporting evidence addressing that argument. Gilead also wishes to advise the Court that an issue previously resolved by stipulation of the parties was reopened by Mylan in its Answering Brief, and that the Court will now need to consider whether or not the phrase “fixed dose combination” from the preamble of the asserted claims is a limitation on those claims.

## II. ARGUMENT

### A. The Court Should Defer Consideration of Mylan’s Indefiniteness Argument Until The Completion of Discovery

In its Answering Claim Construction Brief, Mylan argues for the very first time that the limitation “less than [10%/1%/0.1%/0.01%] degradation of [TDF] over a 24-hour period” is indefinite, *regardless* of how that claim term is construed. *See* D.I. 107 at 2. But indefiniteness is a validity defense. *See* 35 U.S.C. § 112. As such, Mylan bears the burden of proving indefiniteness by clear and convincing evidence. *Takeda Pharmaceutical Co. v. Zydus Pharmaceuticals USA, Inc.*, 743. F. 3d 1359, 1366 (Fed. Cir. 2014). That validity defense, therefore, should only be considered on a fully-developed record.

From the beginning of the claim construction process, it was Mylan (not Gilead) that identified this particular claim limitation as needing construction. And Mylan, in fact, proposed such a construction. *See* Bassett Decl., Ex. 1 at 2, 4. Nowhere in Mylan’s January 26, 2015 “List of Claim Terms to be Construed and Proposed Claim Constructions” did it assert that the

limitation is indefinite. *See generally id.* Mylan's boilerplate statement that it reserved the right to assert indefiniteness regarding *any* of the asserted claims certainly provided no notice of the argument Mylan now makes. *See id.* at 5.<sup>1</sup>

During subsequent meet and confer sessions (before Gilead filed its opening claim construction brief), Mylan informed Gilead that it intended to argue that *Gilead's* proposed construction for this term should be rejected because it would render certain of the asserted claims indefinite. *See D.I. 100 at 17 n.7.* Mylan provided no information to Gilead regarding the substance of any such argument. And, Mylan certainly never stated that it would argue that, even construing the claim term as Mylan proposed, the term would be indefinite.<sup>2</sup> As stated in Gilead's Opening Brief (and not disputed by Mylan in its Answering Brief), Gilead obviously could not respond to such an indefiniteness argument "before it has been made, and before any supporting evidence has been brought to light." *Id.*

Under the briefing schedule ordered by the Court, Gilead has no right of reply and therefore has no opportunity to respond in writing with supporting evidence to this newly-minted argument on which Mylan bears the burden of proof. Gilead would thus be unfairly prejudiced if the Court were to consider Mylan's argument at this time based on an incomplete record. Accordingly, the Court should defer consideration of Mylan's belated indefiniteness argument for this reason alone.

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<sup>1</sup> Mylan also has made no mention of this invalidity argument in any of its discovery responses. In response to an interrogatory requesting that Mylan state the basis for its contention that any asserted claim is invalid or unenforceable for reasons other than anticipation or obviousness, Mylan's sole argument with respect to the '397 patent is that "one or more claims of the '397 patent are invalid for failure to comply with the enablement and/or written description requirements of 35 U.S.C. § 112." (Bassett Decl., Ex. 4 at 6-8.) Mylan did not assert that any of the asserted claims are invalid as indefinite.

<sup>2</sup> Indeed, the fact that Mylan instead consistently proffered its own construction for the term strongly insinuated exactly the opposite: if the claim term were "indefinite," then how could Mylan offer any proposed construction at all?

Moreover, even if Mylan had provided Gilead with proper notice of its indefiniteness argument, “the weight of the jurisprudence disfavors indefiniteness determinations at the *Markman* stage of patent litigation.” *See CSB-System Intern. Inc. v. SAP America, Inc.*, No. 10-2156, 2011 U.S. Dist. LEXIS 83462, (E.D. Pa. Jul. 28, 2011) (rejecting defendant’s indefiniteness arguments without prejudice to defendant’s right to raise them again during summary judgment proceedings). “[S]everal well-settled principles . . . tend to discourage rulings on indefiniteness at the *Markman* stage.” *Id.* at \*50. “First, there is a high burden of proof on a party challenging the patent based on indefiniteness, which is difficult to meet at the early stages of litigation.” *Id.* “Moreover, a claim is not indefinite simply because the parties disagree concerning construction . . . . In this regard an issued patent is entitled to a statutory presumption of validity.” *Id.* Finally, “unlike a *Markman* proceeding that gives meaning to patent claims, indefiniteness invalidates the claims entirely . . . . As such, this dispositive effect is more appropriately tackled at summary judgment and numerous courts have elected to defer indefiniteness until that time.” *Id.* at \*52. *See also Intergraph Hardware Techs. Co. v. Toshiba Corp.*, 508 F.Supp.2d 752, 773 n. 3 (N.D. Cal.2007) (“[The] indefiniteness argument is inappropriate at the claim construction stage.”).

Deferral is also appropriate because this Court’s Scheduling Order states that “[u]nless parties have obtained an early briefing scheduled from the Court, all dispositive motions should be filed after the close of discovery.” (D.I. 53 at 7.) Mylan has requested no such briefing schedule. Instead, it simply inserted its validity arguments into its Answering Brief addressing claim construction—clearly an attempted end-run around the Court’s Scheduling Order. *See Pharmastem Therapeutics, Inc. v. Viacell Inc.*, No. 02-148 GMS, 2003 U.S. Dist. LEXIS 877, \*2 (D. Del. Jan. 13, 2003) (deferring consideration of indefiniteness where party did not move and

court's scheduling order set forth time for filing of dispositive motions).

For the foregoing reasons, the Court should defer consideration of Mylan's indefiniteness argument until the appropriate time—after fact and expert discovery is complete—when the record and evidence will be fully developed. *See Waddington N. Am., Inc. v. Sabert Corp.*, No. 09-4883, 2010 U.S. Dist. LEXIS 114615, at \*7 (D.N.J. Oct. 27, 2010) (stating that “practical considerations . . . militate against determining indefiniteness prior to the end of fact or expert discovery”).

**B. In the Alternative, Gilead Should be Granted Leave to File a Reply Brief**

Should the Court wish to consider Mylan's indefiniteness argument at this time, then Gilead should be granted leave to submit a reply brief and supporting evidence addressing the substance of Mylan's argument. Gilead would be unfairly prejudiced otherwise. It could not have responded to—let alone anticipated—Mylan's argument before it was made and before the alleged evidence supporting it was identified. This is particularly so given that the alleged support for Mylan's argument consists of (at most) seven paragraphs of expert opinion that have not been tested in any way.

The Court should not consider Mylan's argument—raising for the first time an invalidity defense on which Mylan bears the burden of proof by clear and convincing evidence—in the absence of a written reply by Gilead.

**C. Based on Mylan's Answering Brief, a New Dispute Exists Regarding the “Fixed-Dose Combination” Limitation**

The parties stipulated to a construction for the term “fixed-dose combination.” Yet, incredibly, despite stipulating to that construction, Mylan now argues that this term is not a limitation on the claims after all. Accordingly, the Court will now need to consider whether or not the phrase “fixed dose combination” is a limitation on the claims.

During meet and confer sessions between the parties, Gilead consistently stated that “fixed dose combination” was a limitation that required construction. *See* Bassett Decl. Ex. 2 (2/5/15 email from D. Bassett to T. Krzeminski) (“we cannot accept Mylan’s proposed construction of this term because, among other things, it appears to us to read ‘fixed dose’ out of the claim entirely”). Ultimately, the parties agreed to a construction of “fixed dose combination” and, on February 19, 2015, filed a stipulation with the Court setting forth that (and other) agreed-to-constructions. *See* D.I. 99 at 1-2. Clearly, both parties believed the term “fixed dose combination” was a limitation on the claims; otherwise, the claim term would not require any construction at all. However, it now appears that, despite this agreement and stipulation, there is a live dispute requiring the Court’s decision.<sup>3</sup> Accordingly, at oral argument Gilead intends to argue that the term “fixed-dose combination” is a limitation on the claims. *See* Gilead’s Opening Brief (D.I. 100) at 12 n.5. Should the Court agree, there is no dispute between the parties as to the proper construction of that phrase. *See* D.I. 99 at 1-2.

### III. CONCLUSION

Gilead respectfully requests that the Court defer consideration of Mylan’s indefiniteness argument until after the completion of fact and expert discovery. If such consideration is not to be deferred, the Court should grant Gilead leave to file a reply brief addressing that issue within ten days of the Court’s Order to that effect.

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<sup>3</sup> Mylan’s explanation for its change of heart is that it was unaware until Gilead filed its Opening Brief that Gilead was arguing that any part of the claim preamble is not limiting. D.I. 107 at 6 n.5. That is not true. As early as February 10, 2015, Gilead expressly informed Mylan that the term “chemically stable” in the claim preamble “does not need construction.” *See* Bassett Decl., Ex. 3 (2/10/15 email from V. Ferrera to T. Krzeminski). During a meet and confer session two days later, Gilead again expressly informed Mylan that the “chemically stable” preamble language is not a limitation on the claims and did not require construction. *See* Bassett Decl. ¶ 6. Indeed, Mylan now agrees with this position. *See* D.I. 107 at 6 n.4.

Dated: March 19, 2015

Respectfully submitted,

/s/Chad L. Taylor

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**CERTIFICATE OF SERVICE**

I hereby certify that on March 19, 2015, the foregoing **GILEAD'S MOTION TO DEFER CONSIDERATION OF MYLAN'S INDEFINITENESS ARGUMENT OR, ALTERNATIVELY, FOR LEAVE TO FILE A REPLY** was served upon the attorneys of record for Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. using the CM/ECF system, which will send notification of the filing to the counsel of record for Mylan Inc. and Mylan Pharmaceuticals Inc.

/s/Chad L. Taylor

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